AUG 1 7 2000

K002018

125 High Street Suite 7
Mansfield, MA 02048
Phone: 508-337-8881
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ndo surgical, inc.

510K Summary

1. Sponsor Name

   Sponsor/Manufacturer:
   NDO Surgical, Inc.
   125 High Street, Suite #7
   Mansfield, MA 02048
   Telephone: 877-337-8887
   Contact Individual: Jeff Cerier

2. Device Name

   NDO Surgical, Inc. Overtube

3. Identification of Predicate or Legally Marketed Device

   C. R. Bard Endoscopic Overtube K973500, K942044

4. Device Description

   The NDO Surgical, Inc. Overtube is an extruded, flexible, polyvinyl chloride tube, reinforced with stainless steel wire braiding. The stainless steel reinforcing is fully encapsulated in the PVC tube. The proximal end of the Overtube has a polyurethane flange that is bonded to the tube.

   The NDO Surgical, Inc. Overtube is inserted through the patient's mouth into the esophagus following standard medical procedures. Once in place, the NDO Surgical, Inc. Overtube is used as a channel for passage of an endoscope and/or endoscopic instruments into the esophagus. It is designed and intended for circumstances in which repeated endoscopic intubation may be necessary.

5. Intended Use

   The NDO Surgical, Inc. Overtube is intended for use with an endoscope when repeated endoscopic intubation is anticipated.

6. Comparison of Technological Characteristics

   The NDO Surgical, Inc. Overtube is substantially equivalent to the predicate C. R. Bard Endoscopic Overtube in intended use, technological characteristics of the material compostion and processes used in its application. These characteristics support the concept of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2000

Mr. Jeff Cerier
Director of Product Development
NDO Surgical, Inc.
125 High Street, Suite 7
Mansfield, MA 02048

Re: K002018
NDO Surgical Overtube
Dated: June 29, 2000
Received: July 3, 2000
Regulatory Class: II
21CFR 876.1500/Procode: 78 KOG

Dear Mr. Cerier:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K002018

Device Name: NDO Surgical, Inc. Overtube

Indications For Use:

The NDO Surgical, Inc. Overtube is indicated for endoscopic use when repeated endoscopic intubation is anticipated.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002018

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